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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,432

08/30/2006

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MART0910US

4952

24235 7590 05/15/2009

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

05/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,432	<b>Applicant(s)</b> CARREZ ET AL.	
	<b>Examiner</b> SHEFALI D. PATEL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10-13, 15-17, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 5, 9, 14 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgments***

1. In the reply, filed on January 27, 2009, Applicant amended claims 1, 2, 4-9, 11-18, and 20.
2. In the non-final rejection of August 27, 2008, Examiner objected to the specification for not containing section headings. Applicant amended the specification. Objection is withdrawn.
3. Examiner objected to claims 1, 2, 4, 6, 8, 13, 15, and 17 for minor informalities. Applicant amended said claims. Objections are withdrawn.
4. Currently, claims 1-20 are under examination.

### ***Response to Arguments***

5. Applicant's arguments filed on January 27, 2009, have been fully considered but they are not persuasive:

In regards to claim 1, Applicant argues that Simon does not teach the limitation that “when the needle is withdrawn into the cage until it has moved to the rear of the said hole, the wall which is not traversed by the needle can slide to its up position, lifting the said dog and allowing the cage to separate from the catheter base” (Reply, pages 10-11). In response to applicant's argument that Simon does not teach said limitation, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Simon

Art Unit: 3767

teaches the structure that is capable of said functional limitation, as the dog [50] is capable of being lifted out of engagement with the rim [27] when the needle [12] is withdrawn into the cage [40] and the wall [64] is in the up position (Figure 1 to Figure 2).

In regards to claims 6, 8, 10, 15, 17, and 19, Applicant argues that Ferguson does not teach a trapping device (pages 11-12); however, Ferguson does teach a safety shield [300] that protects a needle point of a needle (column 1, lines 22-24). Also, the teachings of separability of the cage into a front part and a rear part of Ferguson are being applied to the integral, one-piece cage of Simon. Reconstructing a formerly integral structure into various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

In regards to claims 7 and 16, Applicant's arguments (pages 12-13) against the use of Greene in a combination of Simon and Ferguson do not take consideration of the claim limitations, in which the front part of the cage constitutes a nose designed to fit into a catheter base.

The rejections of August 27, 2008, are maintained.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 11-13, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon (US 5,279,591).

Art Unit: 3767

In regards to claim 1, Simon teaches an arrangement (Figures 1-5, needle-catheter assembly [10]) for the insertion, into a vein, of a cannula composed of a short catheter (catheter [13]) with a proximal base (hub portion [22]), where this arrangement [10] includes:

- a. a needle (needle [12]) which has a puncture end (cutting end [15]) and a cage (guard protector housing [40]) which extends the base [22] of the cannula in the proximal direction (Figure 1)
- b. where this cage [40] forms a chamber (hollow body portion [52]) through which the needle [12] slides from a proximal entrance (rearward opening [53]) to a distal exit (forward end opening, *not referenced*) (Figure 1), and is equipped with a trap to hold the puncture end [15] of the needle [12] in the chamber [52] when the needle [12] is withdrawn from the catheter base [22] (Figure 2)
- c. with the cage [40] and the base [22] being equipped with retention resources that combine so as to perform temporary retention of the cage on the base before the puncture end [15] of the needle [12] is trapped in the chamber [52] of the cage [40] (Figure 1), with the said retention resources including an external rim (radially extending ears [27]) formed on the base [22], and an external dog (notches [50]) provided on the cage [40] to be held by this rim [27] (Figure 1) (column 7, lines 32-34)
- d. characterized in that the dog [50] is formed on a mobile device which includes a wall (sidewall segment [64]) traversed by a hole (between forward needle support [56] and longitudinally extending portion [65]) for the passage of the needle [12] so that the passage of the needle [12] in the hole holds the dog [50] in a retention position (Figure 1)

Art Unit: 3767

e. the said wall [64] being mounted to slide in the chamber of the cage in a direction that is transverse to the needle [12], between a down held position (Figure 1) and an up released position (Figure 2), so that when the needle [12] is withdrawn into the cage [40] until it has moved to the rear of the said hole, the wall [64] which is not traversed by the needle [12] can slide to its up position (Figure 2), lifting the said dog [50] and allowing the cage [40] to separate from the catheter base [22] (Figure 2)

In regards to claim 2, Simon teaches that said dog [50] is formed at the end of a wall (inner surface [47]) of the mobile device which is at right angles to the sliding wall [64] (Figures 1-2).

In regards to claims 3 and 12, Simon teaches that said dog comprises a ramp (notches [50]) so that a reverse movement of the cage [40] in the proximal direction causes the dog to lift when the needle [12] no longer traverses said hole (Figure 2).

In regards to claims 4 and 13, Simon teaches that the arrangement [10] includes resources (forward needle support [56] and rearward surface [69]) in order to limit the lifting of the sliding wall [64] in the up position (Figure 2).

In regards to claims 11 and 20, Simon teaches that the arrangement [10] includes resources (inner surface [74] and friction material [59]) to prevent the point of the needle [12] exiting via the entrance [53] of the chamber [52] (column 10, lines 34-50).

Art Unit: 3767

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6, 8, 10, 15, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon, as applied to claims 1 and 2 above, and further in view of Ferguson et al (US 6,796,962).

In regards to claims 6 and 15, Simon teaches that the cage [40] is formed of a rear part which constitutes the chamber [52] and a front part which includes a transverse wall (radially-inwardly extending surface [48]) which closes off the said chamber [52] and which includes the exit from the chamber (Figure 3) (column 7, lines 17-19), this transverse wall [48] forming a slide for the sliding wall [64] of the said mobile device (Figure 1 to Figure 2). Simon does not teach that the rear part and the front part are held together by a click on action of nipples provided on the sides of the transverse wall of the front part, in holes formed in the wall of the chamber of the rear part, or vice versa, since Simon appears to teach that the rear part and the front part of the cage are a one-piece, integral structure (Figure 3). Ferguson et al teaches an arrangement (Figures 1-2) in which a cage (shield [300] with housing [312]) comprises a front part (housing first section [328]) and a rear part (housing second section [330]); said front part [328] and said rear part [330] are held together by nipples/holes (ribs, ridges, etc.) (column 6, lines 66-67 to column 7, lines 1-12). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the front part and the rear part, of the

Art Unit: 3767

arrangement of Simon, with nipples/holes, as taught by Ferguson et al, as an obvious alternate structural design choice to the user, for a means to join the front part and the rear part of the cage together, in the case that the front part and the rear part are separable parts. Also, it has been held that constructing a formerly integral structure, as shown by Simon, in various elements (separable front part and rear part) involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

In regards to claims 8 and 17, in a modified arrangement of Simon and Ferguson et al, Simon teaches that said transverse wall [48] of the front part of the cage [40] includes a nipple (forward needle support [56]) which slides in an oblong aperture (rearward surface [69]) of the sliding wall [64] of the mobile device in order to limit the lifting of the mobile device (Figure 1 to Figure 2).

In regards to claims 10 and 19, in a modified arrangement of Simon and Ferguson et al, Simon teaches that the rear part of the cage [40] is shaped so that the base [22] of the needle [12] slots into the rear part for the puncture operation (Figure 1).

10. Claims 7 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Simon and Ferguson et al, as applied to claims 6 and 15 above, and further in view of Greene et al (US 6,221,047).

In regards to claims 7 and 16, in a modified arrangement of Simon and Ferguson et al, Simon does not teach that the front part of the cage [40] constitutes a nose designed to fit into the



Art Unit: 3767

catheter base [22], since Simon appears to teach that the front part of the cage [40] fits around, and not into, the catheter base [22] (Figure 1). Greene teaches an arrangement [10] (Figures 1-10) in which the front part of a cage (needle cover [22]) constitutes a nose (first end [24]) designed to fit into the axial bore [20] of a catheter base (catheter hub [18]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the front part of the cage, of the modified arrangement of Simon and Ferguson et al, with a nose that fits into a catheter base, as taught by Greene et al, as an obvious alternate structural design choice to the user, for a means to join the cage with the catheter base; since regardless of whether the cage surrounds the catheter base in a connection, as taught by Simon, or the cage fits within the catheter base in a connection, as taught by Greene et al, the cage will be in a position to shield the puncture end of the needle when the needle is withdrawn from the catheter.

#### *Allowable Subject Matter*

11. Claims 5, 9, 14, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In regards to claims 5, 9, 14, and 18, the prior art of record does not disclose or render obvious at the time the invention was made the combination as claimed specifically including resources (such as flexible and elastic lateral legs) to prevent the mobile device returning to the down position after it has reached the up position.

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/  
Examiner, Art Unit 3767  
05/12/2009

/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767